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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,407	04/05/2000	Aaron P. White	920043.406	7308

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EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/543,407	Applicant(s) WHITE ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-74* is/are pending in the application.

4a) Of the above claim(s) *60-64 and 69-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-59,65-68 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This Office Action is responsive to Applicant's response filed July 24, 2002. Claims 1-34, 41-44 and 48-53 have been cancelled. Claims 56-74 have been added. Claims 60-64 and 69-73 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections/Rejections Withdrawn

3. In view of Applicant's amendment the following Objections and Rejections have been withdrawn:

a) Objection to the specification, page 2, paragraph 2 of previous Office action.
b) Objection to the specification, page 2, paragraph 3 of previous Office action.
c) Objection to claim 5, page 3, paragraph 4 of previous Office action.
d) Rejection of claims 18, 25, 34, 44 and 52 under U.S.C. 112, second paragraph, page 3, paragraph 5 of previous Office action.
e) Rejection of claims 3-8, 19-21 and 26-28 under U.S.C. 112, second paragraph, page 3, paragraph 6 of previous Office action.
f) Rejection of claim 7 under U.S.C. 112, second paragraph, pages 3-4, paragraph 7 of previous Office action.
g) Rejection of claim 51 under U.S.C. 112, second paragraph, page 4, paragraph 8 of previous Office action.
h) Rejection of claims 18, 25, 34, 44 and 51under 103(a), pages 6-7, paragraph 10, of previous Office action.

Rejection Maintained

4. The rejection of newly presented claims 56-59, 65-68 and 74 under 35 U.S.C. 102(b) as being anticipated by Kay et al is maintained for the reasons set forth on pages 4-5, paragraph 9 of the previous Office Action.

The rejection was on the grounds that Kay et al teach *agfA* genes from *Salmonella* that have been engineered so that they contain foreign antigens or epitopes. Kay et al teach that the foreign antigen or epitope is foreign to the *Salmonella* and the host cell. Kay et al teach that *E. coli can* be used to express the one or more *Salmonella agfA* genes (page 40). Kay et al teach that *Shigella* or other Enterobacteriaceae can be used in this invention (page 6). Kay et al teach that the bacterial host cell that comprises the recombinant gene is able to express a stable *Salmonella AgfA* fimbrin protein fused to one or more foreign antigens. Kay et al teach that both the *Salmonella*-based antigen and the foreign antigen are able to elicit a response from the immune system of the host animal yielding a multipurpose composition/immunogen (page 23). It would be inherent in the teachings of the prior that the recombinant *agfA* gene would replace the native *agfA* gene.

Since the Office does not have the facilities for examining and comparing applicant's recombinant gene with the recombinant gene of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the recombinant gene of the prior art does not possess the same material structural and functional characteristics of the claimed recombinant gene). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Kay et al fails to meet each and every limitation of the instant claims and therefore fails to anticipate the claimed invention. Applicant urges that Kay et al fails to teach or suggest an AgfA fimbrin amino acid sequence in which at least one fimbrin polypeptide segment is replaced with a heterologous polypeptide antigen segment and the such a chimeric fimbrin polypeptide can assemble to form a stable fimbriae. Applicant urges that Kay et al merely describe how to make attenuated *Salmonella* strains

having a mutated agfA gene. Applicant urges that Kay et al provide a *Salmonella* strain having the agfA gene insertionally inactivated by a chloramphenicol resistance gene which truncates the agfA message and does not result in an AgfA protein having foreign antigen or epitope. Applicant urges that Kay et al mention that a fimbrin protein fused to a foreign antigen to elicit an immune response, no such fusion polypeptide to elicit an immune response was described. Applicant urges that the closet example provided by Kay et al was an enzyme alkaline phosphatase (PhoA) wherein the enzyme is used as a marker to detect the mutated AgfA. Applicant urges that Kay et al fails to teach or suggest a chimeric polypeptide comprising an AgfA fimbrin amino acid sequence as set forth in SEQ ID NO:5 or homologues thereof in which at least one fimbrin polypeptide segment that is present in either SEQ ID NO:5 or the homologue thereof is replaced with a heterologous polypeptide antigen segment that is equal in length to the fimbrin polypeptide segment.

Applicant's arguments filed July 24, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing of the record to show why the isolated nucleic acid molecules of the reference are not the same as the claimed nucleic acid molecule. It is the Examiner's position that Kay et al teach attenuated *Salmonella* able to express a foreign antigen in one or more if its fimbriae and alternatively, the foreign gene is fused to a AgfA protein (pages 4-5). Kay et al teach an expression vector construct comprising an agfA gene that is operably fused to

an open reading frame to a foreign gene to yield a dicistronic gene product. Kay et al teach that the dicistronic gene product able to be expressed in a fimbria of a *Salmonella* or an aggregate comprising such gene product (page 5). Kay et al teach that the invention provides an expression vector construct comprising a stable fimbria or aggregate comprising AgfA protein fused to one or more foreign epitopes (page 5). Limitations such as the heterologous polypeptide antigen segment that is equal in length to the fimbrin polypeptide segment or in which at least one fimbrin polypeptide segment that is present in the homologue of SEQ ID NO:5 is replaced with a heterologous polypeptide antigen segment that is equal in length to the fimbrin polypeptide segment" are being viewed as limitations of design choice. The AgfA fimbrin amino acid sequence as set forth in SEQ ID NO:5 of the claimed invention is 100% identical to the AgfA amino acid sequence of the prior art (Figure 7B). Also see attached sequence alignment. Applicant appears to be arguing limitations that are not in the claims with their assertion that "Kay et al does not describe fusion polypeptides that elicit an immune response". It should be noted that the claims do not recite that the chimeric polypeptides encoded by the recombinant nucleic acid of the invention are required to elicit an immune response. However, Kay et al does disclose that the use of fimbriae or aggregates comprising AgfA protein fused to a foreign antigen that elicit an immune response in an animal (page 5). The Examiner agrees that the teachings of the prior art discloses how to make attenuated *Salmonella* strains having a mutated agfA gene, provides a *Salmonella* strain having the agfA gene insertionally inactivated by a chloramphenicol resistance gene which truncates the agfA message and discloses an

enzyme alkaline phosphatase (PhoA) wherein the enzyme is used as a marker to detect the mutated AgfA, these are all examples of foreign epitopes inserted into the AgfA gene. However, Applicant has provided no side-by-side comparison to show that the nucleic acid molecule that encodes a chimeric AgfA fimbrin polypeptide of the claimed invention are different from the nucleic acid molecule that encodes a chimeric AgfA fimbrin polypeptide disclosed in the prior art. Therefore, it would be reasonable to expect barring evidence to the contrary, that the nucleic acid molecule of the claimed invention and the nucleic acid molecule of the prior art are the same.

Status of Claims

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
October 8, 2002

MARK NAVARRO
PRIMARY EXAMINER